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13. Abstract *(Maximum 200 Words)* *(abstract should contain no proprietary or confidential information)*

Lymphedema of the arm is a common, yet dreaded consequence of breast cancer treatment that can result in substantial functional impairment and distress in affected women. Axillary surgery and radiation treatment are known risk factors for lymphedema. However, other potentially modifiable characteristics or behaviors that may influence risk of this condition have not yet been studied. In this study, we will assess whether modifiable factors, including body weight, physical activity, smoking and breast reconstruction, influence risk of arm lymphedema among women treated for breast cancer. Women aged 21-74 years diagnosed with a first primary invasive breast cancer will be identified through a population-based cancer registry. Enrollment will be limited to women who have had axillary node dissection, as the occurrence of lymphedema is most common in these women. The incidence and timing of arm edema following breast cancer will be assessed using physical measures (arm volume) and self-report of symptoms, at regular intervals throughout the study. Each time they undergo arm measurement, women will complete questionnaires detailing and updating information on the exposures of interest and potential confounding factors. The study will be conducted over a 4-year period.

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INTRODUCTION

Lymphedema of the arm is a common, yet dreaded consequence of breast cancer treatment that can result in substantial functional impairment and distress in affected women. Axillary surgery and radiation treatment are known risk factors for lymphedema. However, other potentially modifiable characteristics or behaviors that may influence risk of this condition have not yet been studied. In this study, we will assess whether modifiable factors, including body weight, physical activity, smoking, and breast reconstruction, influence risk of arm lymphedema among women treated for breast cancer. Women aged 21-74 years diagnosed with a first primary invasive breast cancer will be identified through a population-based cancer registry. Eligible women will be residents of King County, Washington. We aim to include approximately 500 women in the study cohort. Enrollment will be limited to women who have had axillary node dissection, as the occurrence of lymphedema is most common in these women. The incidence and timing of arm edema following breast cancer will be assessed using physical measures (arm volume) and self-report of symptoms, at regular intervals throughout the study. Each time they undergo arm measurement, women will complete questionnaires detailing and updating information on the exposures of interest and potential confounding factors. The study will be conducted over a 4-year period.

BODY

Research Accomplishments associated with tasks outlined in the Statement of Work are as follows:

Task 1. Develop Plan for Initial and Follow-up Interviews and Measurements, Months 1-3.

All of these tasks have been performed.

a. Final IRB approval will be obtained.

IRB approval has been obtained from the Fred Hutchinson Cancer Research Center and from the DOD.

b. Tracking system will be created to track patient contacts, recruitment, and interviews.

The tracking system for this study has been developed and is in use.

c. Cohort ascertainment through the CSS tumor registry will be initiated.

We are actively identifying potential study participants through the CSS tumor registry. Case-finding through the registry is updated every month.

d. Enrollment questionnaire will be developed, piloted and finalized.

The enrollment questionnaire has been developed, piloted and finalized. It is now in use.

e. *Interviewer will be trained on study procedures, measurement, and interview administration.*

Interviewer training on all study procedures, including measurement and interview administration, has been completed.

Task 2. Subject Recruitment and Initial Data Collection, Months 4-18

a. Potential study subjects will be contacted, and physician notification will be performed.
These procedures are now ongoing. The first set of contacts with physicians and study subjects occurred after all Human Subjects approvals were obtained in May, 2003. As of mid-August, 2004, we had identified 464 eligible women. The status of these women in the study is as follows:

Deceased, before contacted:	7
Physician notification/ response in process:	31
Physician refusal:	17
Physician notified, subject not yet contacted:	3
Study subject refusal:	45
Subjects contacted, not yet enrolled:	98
Subjects contacted, enrollment interview scheduled:	50
Subjects contacted, enrollment interview complete:	213

b. Participant enrollment interviews and initial measurements will be conducted.
We have completed 213 enrollment interviews, with an additional 50 interviews scheduled for the near future.

Subject recruitment and initial data collection is still ongoing. The number of subjects shown above reflects recruitment during the first 22 months of the study. Recruitment for the study has been slower than anticipated, due to the following: (1) The funding period for this study began on October 1, 2002. The DOD approval to involve human subjects in the research was received in April, 2003. Hence, we did not begin activities related to Task 2 until May, 2003 (month 8), and anticipated that the subject recruitment period would need to extend further into the study period than was originally planned. (2) The number of eligible women is also somewhat lower than expected, which we believe is due to the increasingly widespread use of sentinel biopsy of lymph nodes, with resultant decline in axillary dissection. (3) Some women are not identified by the cancer registry as eligible until a longer time period after diagnosis than we had originally expected. This can occur related either to reporting delays or to the use of neoadjuvant chemotherapy for some months prior to axillary dissection.

c. Follow-up questionnaires will be developed, piloted and finalized.
The follow-up questionnaire has been developed and finalized.

d. Data management and programming to create analytic data files for the enrollment questionnaire and arm measurement data will be performed.
These tasks have been completed.

Task 3. Follow-up Interviews and Data Collection, Months 10-45

a. Follow-up interviews and measurements will be conducted (every 6 months for the first 18 months after enrollment interview, and annual follow-up thereafter).
Follow-up interviews have been initiated. To date, 72 follow-up interviews have been conducted, with an additional 21 scheduled and 19 women in process. We anticipate that the conduct of follow-up interviews may extend several months beyond month 45, into a planned

no-cost extension, due to the delay in initiating study enrollment as described above under Task 2.

b. Data management and programming to create analytic data files from the follow-up questionnaires, surgical and radiation treatment summaries, and repeat arm measurement databases will be performed.
These tasks will be conducted during the later months of the study (e.g., month 40 and beyond).

c. Identification of women with lymphedema by arm volume measures, and comparison with self-report.
These tasks will be conducted during the later months of the study (e.g., month 40 and beyond).

Task 4. Data Analysis and Report Writing, Months 37-48.
These tasks will be conducted during a planned no-cost extension of the project, reflecting the delay experienced in initiating participant enrollment.

KEY RESEARCH ACCOMPLISHMENTS
None to date, as expected at this phase of an observational study.

REPORTABLE OUTCOMES
None to date.

CONCLUSIONS
In this early phase of the study, there are no completed research results.

REFERENCES
None

APPENDICES
None